



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus Optical Co., Ltd.
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K021179
Trade/Device Name: Olympus Disposable Guidewire, Models G-205-3545S and
G-205-3545A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated (Date on orig SE ltr): April 11, 2002
Received (Date on orig SE ltr): April 15, 2002

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of July 5, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021179

Device Name:

Disposable Guidewire G-205-3545S, G-205-3545A

Indications for Use:

This instrument has been designed to be use with Olympus Endo-therapy Accessories. The instrument is used as guidewire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
Counter Use
(Per 21 CFR 801.109)

OR

☐ Over-The-

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021179

(Optional Format 1-2-96)

JUL 5 2002

SMDA 510(k) SUMMARY

10621179

A. Submitter's Name, Address, Phone and Fax Numbers

1. Submitter's Name

Name & Address of manufacturer: Olympus Optical Co., Ltd.
2-3-1 Shinjyuku Monolis Nishi-Shinjuku,
Shinjyuku-ku Tokyo, 163-0914 Japan
Registration No.: 8010047
Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,
of R&D Department, Hachioji-shi, Tokyo 192-8507
Endoscope Division Japan
TEL 81- 426-42-5177
FAX 81-426-46-5613

2. Manufacturer site/Sterilization site

Name & Address of manufacturer: Ashitaka Factory of Terumo Corporation
150, Mainmaigi-cho, Fujinomiya-City
Shizuoka, 418-0015, Japan
9681834
Registration No. □

B. Name of Contact Person

Name: Ms. Laura Storms-Tyler
Address, Phone and Fax Numbers: Olympus America Inc.
Two Corporate Center Drive
Melville, New York 11747-3157
TEL: (631) 844-5688
FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name: Disposable Guidewire G-205-3545S, G205-3545A
Common Name: Guidewire
Classification: Endoscope and accessories 21 CFR 876.1500
Predicate Device: Guide Wire G35-2LB (Olympus Optical Co.,Ltd.) #K933110
Climber (Terumo) #K971937
Lagwire 5658-1/5659-1 (Boston Scientific) #K922302

D. Description of the Device(s)

G-201-35-45, G-202-35-45 are resin-treated coated guidewire. Removal of the guidewire is not necessary during sphincterotomy. G-201-35-45 is straight distal portion type, G-202-35-45 is angle distal portion type. These instruments have been designed to be used with Olympus Endo-Therapy Accessories, which are applicable for $\phi 0.89\text{mm}$ (0.035 inch) diameter guidewires. These instruments are equipped with Laser-markers at the distal portion to conform guidewire placement under fluoroscopy endoscopic maneuvering.

E. Intended Use of the Device(s)

This instrument has been designed to be use with Olympus Endo-therapy Accessories.

The instrument is used as guidewire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, Disposable Guidewire G-205-3545S, G-205-3545A does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.